

REMARKS/ARGUMENTS

Claims 1-20 are active. No new matter has been added. Favorable consideration of this amendment and allowance of the application are respectfully requested.

Rejection—35 U.S.C. §112, first paragraph

Claims 1-4 and 8-11 were rejected under 35 U.S.C. 112, first paragraph, as lacking enablement. The Official Action indicates that the claims are enabled for a method of preparing a selenium yeast product, as well as the resultant yeast product, from *Saccharomyces*. Therefore, in view of the amendments above, this rejection is moot.

Rejection—35 U.S.C. §112, second paragraph

Claims 1-11 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in view of the amendments above.

Rejection—35 U.S.C. §102 or §103

Claims 7-8 were rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, as being obvious over Nogadawithana et al., U.S. Patent No. 4,530,846. Claims 7 and 8 are directed to *Saccharomyces* yeast or yeast products produced using the cultivation method of Claim 1.

Claims 7-14 relate to *Saccharomyces* yeasts or yeast products made using specific cultivation steps described in Claim 7. These method steps produce a product containing particular amounts of organic and inorganic selenium compounds. They also distinguish the claimed products from prior art products made using other cultivation steps as will be explained below.

Initially, to serve as an anticipation when a reference is silent about the asserted inherent characteristic (e.g., an at least 55% content of L-selenomethionine), such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill, Continental Can. Co. USA v. Monsanto Co., 20 USPQ2d 1746, 1749 (Fed. Cir. 1991), see also MPEP 2131.01 (III).

For purposes of anticipation, the Office has not shown that the missing descriptive matter in Nogadawithana, namely, the L-selenomethionine content and inorganic selenium content required by Claim 7, is necessarily present in the yeasts produced by the prior art processes. The selenium yeast product of Claim 7 requires: (i) a content of organic selenium compounds corresponding to a range between 1,000 and 1,600; (ii) a content of L-selenomethionine constituting at least 55% of the total selenium content; and (iii) a content of inorganic selenium compounds not exceeding 1% of the total selenium content. The Office has not shown that the prior art yeasts necessarily meet these limitations and one of skill in the art would not expect the prior art yeast to necessarily meet these selenium content limitations.

While the selenium yeast product disclosed in Nogadawithana is characterized by an intracellular organically bound selenium content of at least 1,000 ppm (column 2 lines 52-53), it would not be expected to have the organic and inorganic selenium content of Claim 7 because there are several significant differences between the cultivation method required by Claim 7 and the prior art cultivation methods.

Those of ordinary skill in the art would have recognized that differences between the methods lead to products possessing different characteristics, including different selenium content. For example, in Nogadawithana it is demonstrated that a small change in how the

sodium selenite was added (compare Examples 1-6 with Example 7) had a great impact on the selenium content and recovery of the selenium yeast product, see the Table in col. 6. Furthermore, the present specification discloses in example 4 (pages 17-18) that the conventional use of molasses as a source of carbon instead of glucose resulted in a selenomethionine content of only 49% versus 73%. Thus, even slight differences between the prior art methods and the method of the invention would have been expected to lead to significantly different products.

In view of the above, the Office has not shown that the prior art processes which do not conform to the process steps in Claims 1 and 7 would necessarily result in similar cultivated yeast products and the anticipation rejection should be withdrawn.

Moreover, the prior art does not disclose or suggest the process steps of Claims 1 and 7, nor does it provide a reasonable expectation of success for producing the product of Claim 7 having specific levels of organo- and inorganic selenium. Accordingly, the Applicants respectfully request that both grounds of rejection over Nogadawithana be withdrawn.

Rejection—35 U.S.C. §103

Claims 1-11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nogadawithana et al., U.S. 4,530,846 and Demicri et al., J. Agric. Food Chem., in view of Schrauzer, J. Nutrition.

Nogadawithana has been addressed above and does not disclose or suggest that the cultivation steps required by Claims 1 and 7 would produce yeasts having the organic and inorganic selenium contents required by Claim 7.

The Office acknowledges that the use of glucose as the sole carbon source is not disclosed in Nogadawithana but argues that the use of glucose is taught in Demicri et al. However, the sole use of glucose is not disclosed, since cane molasses medium is one of

many media contained in the medium blends in the reactor (Demicri, page 2492, first column lines 45-51). Furthermore, Demicri indicates at (page 2,493, first column lines 25-28 that "these results **confirmed the requirement** for the cane molasses supplement, a good source of vitamins and minerals, which was ideal for our purpose (emphasis added)" do not motivate the skilled person to use glucose as the sole carbon source, rather it points away. Cane molasses is a complex nutrient source and significantly different for yeast cultivation purposes than use of glucose or maltose as a single carbon source as shown by the inventors. Thus, Demicri does not suggest the use of glucose or maltose as a sole carbon source and for this reason the rejection does not disclose or suggest combining all the elements of the invention.


The Official Action also acknowledges that the use of minimal medium is not disclosed in Nogadawithana but argues that the use of minimal medium is taught by Demicri. However, Demicri describes the medium as "a medium with minimal sulphur and methionine concentrations" (page 2491 lines 2-3 of the abstract), and an "optimum medium with minimal sulphate" (page 2,795 first column lines 4-5). The skilled person would not consider the medium disclosed by Demicri as a minimal medium but rather a selective medium. The specification, page 5, lines 26-27 define "Minimal medium: Medium containing the minimum amount of nutrients necessary for obtaining yeast growth". Demicri and Nogadawithana do not disclose such a minimal medium. Thus, the prior art does not provide any motivation for cultivating yeast in a minimal medium as opposed to a selective medium, and one with skill in the art would recognize that minimal and selective media are not biological equivalents. Accordingly, the Applicants respectfully request that this rejection be withdrawn, since the prior art does not disclose or suggest *Saccharomyces* yeast or yeast products made by cultivation in a minimal medium having the organoselenium and inorganic selenium content required by Claim 7.

Conclusion

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. An early notice to that effect is earnestly solicited.

Respectfully submitted,

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A handwritten signature in dark ink, appearing to read "Thomas M. Cunningham", is written over a horizontal line.

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